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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/565,538	01/23/2006	Dominique Swinnen	282186US0PCT	2109	
22859 7590 11/05/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET			EXAM	EXAMINER	
			KUMAR, SHAILENDRA		
ALEXANDRIA, VA 22314		ART UNIT	PAPER NUMBER		
			1621		
			NOTIFICATION DATE	DELIVERY MODE	
			11/05/2008	ELECTRONIC	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com oblonpat@oblon.com jgardner@oblon.com

## Application No. Applicant(s) 10/565,538 SWINNEN ET AL. Office Action Summary Examiner Art Unit SHAILENDRA -. KUMAR 1621 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 08 August 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-6.9-21 and 24-30 is/are pending in the application. 4a) Of the above claim(s) 24 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-6.9-11 and 25-30 is/are rejected. 7) Claim(s) 12-21 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date 4/9/06

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Application/Control Number: 10/565,538

Art Unit: 1621

#### DETAILED ACTION

This office action is in response to applicants' communication filed on 8/8/08.

Claims 1-6, 9-21 and 24-30 are pending in this application.

Applicant's election with traverse of Group I, drawn to claims 1-6, 9-11, 12-21 and 25-30. when Cy is aryl and A is non heteroaryl in the reply filed on 8/8/08 is acknowledged. The traversal is on the ground(s) that the Examiner has not carried out the burden of providing any reasons or examples to support conclusions that the claims of the restricted groups are patentably distinct or lack unity of invention. The Examiner asserts that Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 and 13.2 because they lack the same corresponding technical feature. The Examiner, however, has not considered that the claims in each group are considered related inventions under 37 C.F.R. 1.475(b) in which the inventions are considered to have unity of invention. Applicants submit that while PCT Rule 13.1 and 13.2 are applicable, 37 C.F.R. 1.475(b) provides in relevant part that "a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to ...(3) a product, process for the manufacture of said product and/or the use of said product. Moreover, Applicants respectfully submit that a search of all the claims would not impose a serious burden on the Office. As the Office has not shown any evidence that a Restriction Requirement should now be required when the International Preliminary Report did not, restriction is believed to be improper.

In chemical cases, a specified group of materials which do not necessarily belong to an otherwise class can be claimed together employing "Markush" language. Tile Markush practice sanctions the claiming together operable substances which could not be defined by generic language but which nevertheless have a community of chemical or physical characteristics. The member of the Markush group need only possess at least one property in common which is mainly responsible for the function of the chemical relationship. The same utility in a generic sense suffices.

Further, M.P.E.P. § 803 states as follows: "If the search and examination of an entire application can be made without a serious burden, the Examiner must examine it or the merits even though it includes claims to distinct and independent inventions."

Applicants submit that a search of all the claims would not constitute a serious burden on the Office. In fact, the International Search Authority has searched all the claims together. This is not found persuasive because as stated in the restriction requirement, A and Cy are such disparate chemical groups that ,there will be undue burden to search entire application, and inasmuch as these groups are divergent groups, they lack the same or corresponding technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Page 3

Application/Control Number: 10/565,538

Art Unit: 1621

Applicants further elected a species of example 36 on page 105.

Thus claims 1-6, 9-21, and 25 -30 will be examined to the extent they read on when Cy to be anyl and A to be non heterocyclic groups.

#### Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which
papers have been placed of record in the file.

#### Information Disclosure Statement

 The information disclosure statement (IDS) submitted on 4/19/ 06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-11 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261,270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731,737, 8USPQ2s 1400, 1404 (Fed. Cir. 1988). MPEP 2164.01(a) states "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue". The factors are applied below to the instant claims.

#### The breadth of the claims

Application/Control Number: 10/565,538

Art Unit: 1621

The claims are drawn to products of Formula I with the scope as defined in claim 1.

The nature of the invention

The genus of compounds are claimed to possess PTP 1B inhibiting activity.

## The state of the prior art/level of ordinary skill/level of predictability

The level of ordinary skill is high, but the level of predictability in the art is low, supra. There is no art known correlation between structure/function for this class of compounds. Absent guidance, one of ordinary skill would not know whether the compounds embraced by the claimed genus would possess PTP1B inhibiting activity.

The amount of direction provided by the inventor/existence of working examples Example 1: tested and shown to possess PTP1B inhibiting activity

Examples 2-82: it is unclear from the disclosure whether these compounds were tested for PTP 1B inhibiting activity. Applicant is invited to submit an affidavit clarifying whether these compounds were tested and whether they possess PTP 1B inhibiting activity.

### The quantity of experimentation needed to make or use the invention

It is not known what compounds of the broad genus claimed, other than compound of Example 2, possess activity as inhibitors of PTP1B. The skilled artisan would be subject to undue experimentation to test the compounds for this activity before being able to practice the invention commensurate in scope with the breadth of the claims.

The elected species appears to be free of prior art and is allowable.

US 2006/0189583 and US 7,053,245 are cited to show the state of the art. See the abstract in both the references.

- 4. Claims 12-16, 17-20 and 21 are objected to as containing subject matter of non elected claims, but would be allowable if rewritten in independent form including all of the limitations of the elected species and closely related compounds.
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30. Alt Fri.

Art Unit: 1621

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHAILENDRA - KUMAR/ Primary Examiner, Art Unit 1621

S. Kumar 10/31/08